IN EFFECT 8/7/2007

- R70. Agriculture and Food, Regulatory Services.
- R70-330. Raw Milk for Retail.
- R70-330-1. Authority.
 - A. Promulgated under the authority of Section 4-3-2.
- B. Scope: This rule establishes the requirements for the production, distribution, and sale of raw milk for retail.
- C. History: The Utah Department of Agriculture and Food, with the concurrence of the U.S. Food and Drug Administration (FDA) strongly advises against the consumption of raw milk. There are numerous documented outbreaks of milkborn disease involving Salmonella and Campylobacter infections directly linked to the consumption of un-pasteurized milk. Cases of raw milk associated campylobacteriosis have been reported in the states of Arizona, California, Colorado, Georgia, Kansas, Maine, Montana, New Mexico, Oregon, Pennsylvania, and Utah. An outbreak of samonellosis, involving 50 cases was confirmed in Ohio in 2002. Recent cases of Escherichia coli (E. coli) 0157:H7, Listeria monocytogenes, and Yersinia enterocolitica infections have also been attributed to raw milk consumption.

R70-330-2. [Raw Milk Defined.] Definitions.

[Raw milk for retail shall be milk as defined by law that has not been pasteurized. The word milk shall be interpreted to include the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy hoofed mammals.]

- A. "Raw milk" means milk as defined by law that has not been pasteurized, or heat treated. The word milk shall be interpreted to include the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy hoofed mammals.
- B. "Properly staffed" means a person or persons on premise available to sell milk, exchange money, and lock and secure the retail store.
- C. "Quarterly pathogen testing verification" means a sample from the Raw for Retail batch is aseptically split by the Regulatory agency and tested for the prescribed pathogens at both the independent laboratory and the department laboratory and the results are evaluated and compared.
- D. "Department" means the Utah Department of Agriculture and Food.

R70-330-3. Permits.

A permit shall be required to sell raw milk for retail. Such permit shall be suspended when these rules or applicable sections of the Utah Dairy Act, Utah Code Annotated (UCA), Vol. 1, Title 4, Chapter 3, are violated. Cow-share programs, as defined in the Utah Dairy Act, shall not be allowed, either in conjunction with a permitted raw for pasteurization dairy, a permitted raw milk for retail dairy, or in lieu of a permit to sell raw milk for retail.

R70-330-4. Building and Premises Requirements.

The building and premises requirements at the time of the issuance of a new permit shall be the same as the current Grade A building guidelines. In addition to these guidelines, there shall be separate rooms provided for (1) packaging and sealing of raw milk, (2) the washing of returned multi-use containers when applicable, and (3) a sales room for the sale of raw milk in a properly protected area that is not located in any of the milk handling rooms. These rooms shall meet or exceed the construction standards of a Grade A milkhouse. <u>If the Raw for Retail dairy also</u> raises chickens ,or other poultry, for meat and/or eggs, their housing and movement shall be restricted to areas that do not include the milkhouse, milk barn and their immediate surroundings, the corrals and <u>alleys where there is normally cows or goats</u>, and other locations where there is normal cow or qoat traffic. They shall also be restricted from areas normally considered traffic areas of the raw milk customers.

R70-330-5. Sanitation and Operating Requirements.

- [A. The Utah Department of Agriculture and Food, with the concurrence of the U.S. Food and Drug Administration (FDA) strongly advises against the consumption of raw milk. There are numerous documented outbreaks of milkborne disease involving Salmonella and Campylobacter infections directly linked to the consumption of un pasteurized milk. Cases of raw milk associated campylobacteriosis have been reported in the states of Arizona, California, Colorado, Georgia, Kansas, Maine, Montana, New Mexico, Oregon, Pennsylvania, and Utah. An outbreak of samonellosis, involving 50 cases was confirmed in Ohio in 2002. Recent cases of E. coli 0157:H7, Listeria monocytogenes, and Yersinia enterocolitica infections have also been attributed to raw milk consumption.]
- $[\underline{\mathtt{B}}]\underline{\mathtt{A}}.$ Sanitation and operating requirements of all raw milk facilities shall be the same as that required on a Grade A dairy farm producing milk for pasteurization. Milk packaging areas and container washing areas at the raw milk facilities shall meet the requirements for Grade A pasteurized milk processing plants.
- [E]B. All milk shall be cooled to 50 degrees F. or less within one hour of the commencement of milking and to 41 degrees F. or less within two hours after the completion of milking[7]. [provided that the blend temperature after the first milking and subsequent milkings does not exceed 50 degrees F. Milk not handled in this manner may be deemed adulterated and shall not be sold.]
- C. The blend temperature after the first milking and subsequent milkings shall not exceed 50 degrees. Milk not handled in the manner required in this subsection and subsection "B" above shall be deemed adulterated and shall not be sold.
- 1. All raw for retail farm bulk milk tanks shall be equipped with an approved temperature-recording device, in addition to the indicating thermometer.
- 2. The recording device shall be operated continuously and be maintained in a properly functioning manner. Circular

recording charts shall not overlap.

- 3. The recording device shall be verified as accurate every six (6) months and documented in a manner acceptable to the department.
- 4. Recording thermometer charts shall be maintained on the premises for a minimum of six (6) months and available to the department.
- 5. The recording thermometer shall be installed near the milk storage tank and accessible to the department.
- 6. The recording thermometer shall comply with the current technical specifications in the Pasteurized Milk Ordinance (PMO) for tank recording thermometers.
- 7. The recording thermometer charts shall properly identify the producer, date, and signature of the person removing the chart.
- D. [The sale and delivery of raw milk shall be made on the premise where the milk is produced and packaged. The sale shall be to consumers for household use and not for resale. The sale of block cheese, when held at 35 degrees F. for 60 days or longer, may be sold at retail or for wholesale distribution, at locations other than the premise where the milk was produced.] The temperature of the milk at the time of bottling shall not exceed 41 degrees F.
- [All products made from raw milk including cottage cheese, buttermilk, sour cream, yoqurt, heavy whipping cream, half and half, butter, and ice cream shall not be allowed for sale in Utah to individual consumers due to potential negative public health implications of such products.] The sale and delivery of raw milk shall be made on the premise where the milk is produced and packaged, or at a self owned, properly staffed, retail store. Sanitation and construction requirements of the facilities used as self owned, retail stores shall be the same as those contained in the Wholesome Food Act, Title 4 Chapter 5. Transportation shall be done by the producer with no intervening storage, change of ownership, or loss of physical control. The temperature of the milk shall be maintained at 41° F or below. Each display case shall have a properly calibrated thermometer, and a daily temperature log shall be maintained and made accessible to the Department.
- F. Raw Milk block cheese, when held at 55 degrees F. for 60 days or longer, may be sold at retail stores or for wholesale distribution, at locations other than the premise where the milk was produced.
- G. Except as provided in part (F) above, all products made from raw milk including, but not limited to, cottage cheese, buttermilk, sour cream, yogurt, heavy whipping cream, half and half, butter, and ice cream shall not be allowed for sale in Utah.
- H. Milk that has been heat treated, shall not be labeled as "Raw Milk" for retail sale.
- I. Inspections of the self owned retail store shall be performed no less than four times per year to insure compliance with the sanitation, construction, and cooling requirements as set

R70-330-6. Testing.

- A. Raw Milk for Retail Testing.
- 1. [The requirements, standards, and enforcement procedures for testing raw milk for retail to include: added water, antibiotics, pesticides, and/or other adulterants shall be the same as those used for raw milk for Grade A.] Unpackaged Raw Milk
- a. The Department shall collect a representative sample of milk from each Raw for Retail farm bulk tank once each month. All samples shall be delivered to the State Dairy Testing Laboratory. Tests shall include those prescribed for Raw Milk for Pasteurization as found in the PMO, and in addition shall include added water, and/or other adulterants. Whenever a sample result fails to meet a standard in any of the prescribed categories, the Raw for Retail permit shall be suspended until such time as a compliant sample can be obtained by the Department or a contracted approved independent laboratory, meeting PMO/Department standards, and until an inspection can be performed at the facility by the Department. All expenses for the re-sampling, re-testing, and re-inspecting shall be born by the producer as per the Department's fee schedule. At such time as the above criteria are met, the Raw for Retail permit shall be fully reinstated.
- b. The standards for testing Somatic Cell Count (SCC) in raw milk for retail shall be, the Somatic Cell Count shall not exceed 350,000 cells per milliliter (ml) for cows, and not to exceed 1,000,000 ml for goats. The requirements for sampling, and the enforcement procedures for SCC shall be the same as those set forth in 1.a. above.
- c. The bacterial standards shall be a Standard Plate Count (SPC) of no more than 20,000 per ml. and a coliform count of no more than 10 per ml.
- 2. [The requirements, standards, and enforcement procedures for testing for Somatic Cell Count (SCC) in raw milk for retail, shall be that the Somatic Cell Count shall not exceed 350,000 cells per milliliter (ml).] Packaged Raw Milk sold on Premise
- a. It shall be the responsibility of the Department to collect a representative sample of packaged raw milk once each month. All samples shall be delivered to the State Dairy Testing Laboratory. Tests shall include those prescribed for Grade "A" Pasteurized milk as found in the PMO. Whenever a sample result fails to meet a standard in any of the prescribed categories, the Raw for Retail permit shall be suspended until such time as a compliant sample can be obtained by the Department or a contracted approved independent laboratory, meeting PMO/Department standards, and until an inspection can be performed at the facility by the Department. All expenses for the re-sampling, re-testing, and reinspecting shall be born by the producer as per the Department's fee schedule. At such time as the above criteria are met, the Raw for Retail permit shall be fully reinstated. When a sample produces a violative Coliform count of more than 10 per mL, the count shall be enumerated and the sample transferred to

appropriate laboratory facilities for pathogen testing.

- 3. [The requirements, standards, and enforcement procedures for testing for bacteria and coliform shall be the same as those prescribed for Grade A pasteurized milk. The bacterial standard shall be a Standard Plate Count (SPC) of no more than 20,000 per ml.; Coliform count shall not exceed 10 per ml.] Packaged Raw Milk sold at Self-Owned Retail Stores
- a. It shall be the responsibility of the producer to have a third party sampler certified by the Department to collect a sample from each batch of milk delivered to the retail store by obtaining one container of milk at the store and submitting it to a certified third party laboratory to be tested for Antibiotic Drug Residue, Standard Plate Count (SPC) and Coliform Count. All containers of milk from the sampled batch shall be withheld from sale until the results of the tests are known. Whenever a sample result exceeds the standard in any of the prescribed categories, the producer shall not allow the milk to enter into commerce and shall dispose of the milk in a manner agreeable to the Department.
- b. It shall be the responsibility of the Department to collect at the operator's expense or oversee collection of a representative sample of packaged raw milk once each month for screening for the presence of Listeria monocytogenes, Salmonella, Campylobacter jejuni, and E. Coli 0157:H7. All samples shall be delivered to the State Dairy Testing Laboratory or other laboratories approved by the department. Test results showing any growth or activity shall be considered positive. If any of the screening test results are positive, then a confirmation test shall be performed.
- Whenever any of the test results for any the prescribed pathogens are positive, the Raw for Retail permit shall be suspended until such time as a compliant sample can be obtained by the Department or contracted approved independent laboratory, meeting PMO/Department standards, and until an inspection can be performed at the facility by the Department. All expenses for the re-sampling, re-testing, and re-inspecting shall be born by the producer as per the Department's fee schedule. At such time as the above criteria are met, the Raw for Retail permit shall be fully reinstated.
- c. A hazard analysis and critical control point (HACCP) System including a milk testing procedure for specified pathogens shall be required, and approved by the department, for all raw for retail dairies.
- d. The HACCP System shall include plans and policies for initiating and conducting a recall in the event of a positive pathogen test result.
- e. The HACCP System shall include the seven following principles:

(i).	Conduct hazard analysis
(ii).	Determine the critical control points
(iii).	Establish critical limits
(iv).	Establish monitoring procedures
(v).	Establish corrective actions
(vi).	Establish verification procedures

- ______(vii). Establish record-keeping and documentation procedures.
- f. Prior to the implementation of a HACCP plan, develop, document and implement written Prerequisite Programs (PPs). The HACCP Plan, along with the PPs becomes the HACCP System. Steps to producing the HACCP Plan and System are found in the U.S. National Advisory Committee on Microbiological Criteria for Food (NACMCF) document.
- g. The HACCP plan shall identify and address points in the production, distribution, transportation and retail display system where the milk may become contaminated or held in conditions that support the growth of pathogens.
- (i). When tests are performed by an independent laboratory, quarterly pathogen testing verification shall be conducted by the Department.
- (ii). Independent laboratories shall participate in an annual split sampling program testing the capacity of the pathogen methodology directed by this rule, and results sent to the Department.
- h. The producer shall recall all milk from the failed batch that is already in commerce.
- i. A database shall be kept and made available for review by both the Utah Department of Agriculture and Food and the Utah Department of Health of all customers, which shall include names, addresses, and telephone numbers of customers, dates of purchases and amounts of milk purchased.
- j. If another agency's epidemiological investigation finds probable cause to implicate a raw for retail dairy in a milk born illness outbreak, the Raw for Retail Permit shall be suspended by the Department until such time as milk samples are pathogen free when analyzed by the Department or other Department approved testing laboratories, and until an inspection can be performed at the facility by a Compliance Officer from the Department.
 - B. Animal Health Tests.
- 1. General herd health examination. Prior to inclusion in a raw milk supply, and each six months thereafter, all animals shall be examined by a veterinarian. Each animal in the herd must be positively identified as an individual. This examination shall include an examination of the milk by [the California Mastitis Test (CMT)] a method recommended by the PMO, shall include a statement of the udder health of each animal, and a general systemic health evaluation.
- 2. Tuberculosis testing. Prior to inclusion in a raw milk supply, each animal shall have been tested for tuberculosis within 60 days prior to the beginning of milk production and shall be retested for tuberculosis once each year thereafter. All positively reacting animals shall be sent to slaughter in accordance with R58-10 and R58-11.
- 3. Brucellosis testing. Each animal from which raw milk for retail is produced shall be positively identified as a properly vaccinated animal or shall be negative to the official blood test for brucellosis within 30 days prior to the beginning of each lactation. All positively reacting animals shall be sent to

slaughter in accordance with R58-10 and R58-11. Goats and sheep shall be tested once each year for brucellosis with the official blood test and all positively reacting animals shall be sent to slaughter in accordance with R58-10 and R58-11.

- 4. Bulk tank milk testing. All raw milk for retail shall be bulk tank tested at least four times yearly with the brucella milk ring test. If such brucella ring test is positive for brucellosis, then each animal in the herd shall be tested with the official blood test and any reactors found shall be immediately sent to slaughter in accordance with R58-10 and R58-11.
 - C. Personnel Health.

Each employee of the dairy working in the milk handling operation shall obtain a valid medical examination health card signed by a physician and approved by the department once each year [or] and shall hold a valid food handler's permit. No person shall work in a milk handling operation if infected from any contagious illness or if they have on their hands or arms any exposed infected cut or lesion. If there is any question in this regard, the department may ask for an additional certification from a physician that this person is free from disease which may be transmitted by milk.

R70-330-7. Packaging and Labeling.

A. Label Requirements.

The consumer containers for raw milk for retail shall be furnished by the permittee and shall be labeled with the following information:

- 1. The common or usual name of the product without grade designation. The common name for raw milk is "Raw Milk". If it is other than cow's milk, the word "milk" shall be preceded with the name of the animal, i.e., "Raw Goat Milk".
- 2. The name, address, and zip code of the place of production and packaging.
- 3. Proper indication of the volume of the product either on the container itself or on the label.
 - 4. Nutritional labeling information when applicable.
- 5. The phrase: "[Studies have established a direct causal link between gastrointestinal disease and the consumption of raw milk.] Raw milk, no matter how carefully produced, may be unsafe.", shall appear on the label in a conspicuous place. The height of the smallest letter shall be no less than one [sixteenth] half inch.
- 6. [Other provisions of labeling laws in effect in Utah as they apply to dairy/food products.] The shelf life labeling of bottled raw milk shall include a pull date, expiration date, or best-if-used-by date, and shall be displayed and clearly visible on raw milk. Raw milk shall not be sold after the pull date, expiration date, or best-if-used-by date has expired, and the date shall not be more than nine days after packaging.
- 7. Other provisions of labeling laws in effect in Utah as they apply to dairy/food products.
- B. Products not labeled as required shall be deemed misbranded.

KEY: [food] dairy inspection

Date of Enactment or Last Substantive Amendment: June 2, 2004

Notice of Continuation: March 16, 2006

Authorizing, and Implemented or Interpreted Law: 4-3-2